

Claims 15 and 18 are rejected under 35 U.S.C. 101 because they claim a composition of matter comprising a gene (PS128 DNA and PS128 polynucleotides) but these are products of nature and thus are directed to non-statutory subject matter.

Thus, Applicant has amended the claims to include "purified" language and it is requested that this rejection be withdrawn.

Claims 1-6, 11-12, 15 and 18 are rejected under 35 U.S.C. 112, first paragraph. Specifically, the Examiner states that the isolated SEQ ID NO's meet the written description provisions of 35 U.S.C. 112, first paragraph but that the claims are directed to or encompass genes, epitopes, and sequences that have a recited degree of identity which do not meet written description provisions.

Therefore, Applicant submits the software manual to the Wisconsin Sequence Analysis program, Version 8, publicly available from Genetics Computer Group, Madison, WI, as Exhibit A. Support for this submission is found on page 12, beginning on line 10. The manual provides the algorithm, parameters, parameter values and other information necessary to, accurately and consistently, calculate the percent identity. This manual indicates on pages 5-21, *inter alia*, that the software used the local homology algorithm of Smith and Waterman (*Advances in Applied Mathematics* 2; 482-489 (1981)).

Further, the methods for identifying epitopes in a novel peptide sequence are well known and described in both the scientific, commercial, and patent literature. For example, M. H. Van Regenmortel describes how to predict epitopes from the primary sequence of a protein. (See "Protein structure and Antigenicity", *Int J Rad Appl Instrum B*, 14(4):277-80, 1987.)

Additionally, Perkin-Elmer Biosystems, a major provider of DNA sequencing and peptide synthesizing instruments has established a public website which describes how to select peptides which reflect the epitopes of a protein. (See <http://www.pebio.com/pa/340913/html/chapt2.html#Choosing the Epitope>.) This electronic publication was posted in 1996 and basically describes the process employed by the inventors of the current patent application.

In addition, patent application PCT/US97/00485 describes in detail how to identify epitopes from peptide sequences. The sequence can be scanned for

hydrophobicity and hydrophilicity values by the method of Hopp, Prog. Clin. Biol. Res. 172B: 367-377 (1985) or the method of Cease et al, J. Exp. Med. 164: 1779-1784 (1986) or the method of Spouge et al, J. Immunol. 138: 204-212 (1987). Commercial software programs to implement these methods are available. It is therefore respectfully requested that this rejection be withdrawn.

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite. The Examiner states that the language "selectively hybridize," is the reason for this rejection.

Applicant has deleted this language and respectfully requests that this rejection be withdrawn.

The Examiner states applicants claim to priority under 35 U.S.C. 120 to patent 08/838,968 is denied because applicant does not have support for 100% identity of SEQ ID Nos: 1-5 and 12-14 and thus the priority date awarded instant claims is the instant filing date, 4-23-98.

Applicant will clarify:

Seq ID #1 of the instant case is the same as SEQ ID #1 of the parent;

Nucleotides 1-3, 270, 274 and 298-339 SEQ ID #2 of the instant case are new and nucleotides 4-269 are the same as nucleotides 11-276 of SEQ ID #4 of the parent, nucleotides 271-273 are the same as 277 – 279 of SEQ ID #4 of the parent and nucleotides 275-297 are the same as 280-302 of SEQ ID #4 of the parent;

SEQ ID #3 of the instant case is the same as nucleotides 10-214 of SEQ ID #4 of the parent; and

Nucleotides 277, 281 and 305 – 346 of SEQ ID #4 and #5 of the instant case are new, nucleotides 1-276 are the same as nucleotides 1-276 of SEQ ID #4 of the parent, nucleotides 278-280 are the same as 277-279 of SEQ ID #4 of the parent, and nucleotides 282 – 304 are the same as 280-302 of SEQ ID #4 of the parent.

Thus, claims 1-6, 11, 12, 15 and 18 get priority back to the parent (i.e. April 23, 1997) and new claims 19-21 get the instant priority date (i.e. April 23, 1998).

Claims 1-3, 15 and 18 are rejected under 35 U.S.C. 102(a) as being anticipated by any one of the following references alone; GenBank Accession No. AA631976, {31 October 1997}, and GenBank Accession No. AA578209, {11 September 1997}. The Examiner states all accession No.'s teach a fragment sharing a single nucleic acid in common with SEQ ID Nos: 1-5 and that, GenBank Accession No. AA578209, 11 September 1997, teaches a nucleic acid sequence which is 100% identical with SEQ ID NO:2.

Applicant has deleted "fragment" language and raised the percent identity in general and requests that this rejection be withdrawn.

Claims 1-3, 15 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by any one of the following references alone; GenBank Accession No. Z39296, {27 October 1994}, GenBank Accession No. R94063, {1 September 1995}, GenBank Accession No. H72049, {2 November 1995}, GenBank Accession No. H83957, {16 November 1995} and GenBank Accession No. T83743, {1 April 1995}. The Examiner states that all accession No.'s teach a fragment sharing a single nucleic acid in common with SEQ ID Nos: 1-5.

Again, Applicant has deleted "fragment" language and raised the percent identity in general and requests that this rejection be withdrawn.

Claims 1-6, 11-12, 15 and 18 directed to an invention are provisionally rejected as not patentably distinct from claims 10-16, 30, 33, 35, and 38-48 of commonly assigned 09/065,383. Specifically, the Examiner states instant claims drawn to polynucleotide fragments and fragments with a percent identity are encompassed by claims 10-16, 30, 33, 35 and 38-48 because the subject nucleotides are shared in common. Thus, the nucleotides of instant claims are rendered obvious by the claims of the '383 application. The Examiner states that in order to resolve this issue, the assignee is required under 37 CFR 1.78(c) and 35 U.S.C. 132 to show that the conflicting inventions were commonly owned at the time invention in this application was made.



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Amend. & Resp.

Applicant requests that this provisional rejection be held in abeyance until subject matter is deemed allowable.

Claims 1-6, 11-12, 15 and 18 are rejected under 35 U.S.C. 103 (a) as being unpatentable over any one of the following references; GenBank Accession No. AA631976, {31 October 1997}, and GenBank Accession No. AA578209, {11 September 1997}, GenBank Accession No. Z39296, {27 October 1994}, GenBank Accession No. R94063, {1 September 1995}, GenBank Accession No. H72049, {2 November 1995}, GenBank Accession No. H83957, {16 November 1995} and GenBank Accession No. T83743, {1 April 1995}, as set forth above, GenBank. Accession No. N74923, {5 April 1996}, GenBank Accession No. AA280704, {3 March 1997}, GenBank Accession No. Z39296, {27 October 1994}, and GenBank Accession No. N80180 {4 April 1996} in view of Sambrook et al, Molecular Cloning, {1989}, 16.1-16.16.

Again, based on the above mentioned amendments which delete "fragment" language and raise the percent identity, it is respectfully requested that this rejection be withdrawn.

### CONCLUSION

In view of the aforementioned amendments and remarks, the aforementioned application is in condition for allowance and Applicant requests that the Examiner withdraw all outstanding objections and rejections and to pass this application to allowance.

Respectfully submitted,

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A handwritten signature in black ink, appearing to read "P. A. Billing-Medel".

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